

The NCI/VA Agreement on Clinical Trials: Questions and Answers

Key Points

- The NCI/VA Interagency Agreement covers the full range of NCI-sponsored clinical trials, including prevention, diagnostic, and treatment studies (see Question 3).
- Veterans will be able to enroll in trials at participating VA facilities and, in selected cases, in non-VA institutions (see Question 6).
- NCI and VA also will establish closer cooperation in planning future trials (see Question 8).

1. What is the NCI/VA Interagency Agreement?

The National Cancer Institute (NCI) and the Department of Veterans Affairs (VA) signed an Interagency Agreement in January 1997 that is intended to increase the access of eligible veterans to all phases of NCI-sponsored clinical trials and to provide VA clinical researchers with expanded opportunities to participate in clinical cancer research. According to the agreement, VA will provide coverage for eligible veterans to participate in a broad range of clinical trials across the country.

The partnership paves the way for more NCI clinical trials to be carried out in VA facilities. In addition, VA will pay the medical care costs of veterans who enroll in NCI trials in non-VA facilities in selected cases.

The agreement is part of an ongoing effort at NCI to ensure continued and expanded access to clinical trials by eliminating barriers to patient enrollment. This agreement also reflects VA's recent efforts to expand its partnerships and formal relationships with non-VA health care related organizations.

2. What is a clinical trial?

Clinical trials are research studies conducted with people who volunteer to take part. Each study answers scientific questions and tries to find better ways to prevent, screen



for, diagnose, or treat a disease. People who take part in cancer clinical trials have an opportunity to contribute to knowledge of, and progress against, cancer. They also receive up-to-date care from experts.

3. Which clinical trials are covered by the NCI/VA agreement?

The NCI/VA Interagency Agreement covers the full range of NCI-sponsored clinical trials, including prevention, diagnostic, and treatment studies.

Prevention clinical trials study ways to reduce the risk, or chance, of developing cancer. Most prevention trials are conducted with healthy people who have not had cancer. Some trials are conducted with people who have had cancer and want to prevent the return of cancer (recurrence) or reduce the chance of developing a new type of cancer.

Diagnostic clinical trials study tests or procedures that could be used to identify cancer more accurately and at an earlier stage. Diagnostic trials usually include people who have signs or symptoms of cancer.

Treatment clinical trials are conducted with people who have cancer. They are designed to answer specific questions about, and evaluate the effectiveness of, a new treatment or a new way of using a standard treatment. These trials test many types of treatments, such as new drugs, vaccines, new approaches to surgery or radiation therapy, or new combinations of treatments. Included in the NCI/VA agreement are phase I treatment trials, which test the safety of a treatment; phase II trials, which determine whether a treatment is effective in various kinds of cancer; and the larger phase III trials, which compare a widely accepted or “standard” treatment with a new treatment that appeared promising in phase II studies.

4. Which trials are defined as “NCI-sponsored”?

NCI-sponsored trials, for the purpose of the agreement, are:

- Trials reviewed and approved by NCI staff;
- Studies conducted by NCI cooperative clinical trial groups, which are networks of institutions that jointly carry out large clinical trials following the same protocols;
- Studies conducted in clinical and comprehensive cancer centers under an NCI approved protocol review and surveillance mechanism; and
- Protocols performed under the direct support of an NCI peer-reviewed grant.

5. Which veterans are covered by the agreement?

Veterans covered are those who fall into the “mandatory” category under legislation passed by Congress. These include:

- Service-connected veterans (those with a VA determination of a service-related health problem);
- Former prisoners of war;
- Veterans who were exposed to herbicides while serving in Vietnam, to ionizing radiation during atmospheric testing and during the occupation of Hiroshima and Nagasaki, or to an environmental hazard while serving in the Persian Gulf Theater and need treatment for a condition that might be related to such exposures;
- Veterans receiving a VA pension;
- Veterans of World War I;
- Veterans eligible for Medicaid; and
- Veterans who are non-service-connected and whose income is \$21,001 or less if single with no dependents, or \$25,204 or less if married or single with one dependent, plus \$1,404 for each additional dependent.

6. Where can veterans enroll in NCI clinical trials?

Veterans will be able to enroll in trials at participating VA facilities and, in selected cases, in non-VA institutions. VA will define the circumstances under which patients can enroll in trials in non-VA facilities.

VA Medical Centers

Many VA medical centers around the country are already affiliated with NCI’s cooperative groups, the networks of institutions that carry out joint clinical trials. More are expected to participate in NCI cooperative group clinical trials as a result of the agreement. In addition, some VA medical centers that are affiliated with major academic medical centers are already participating actively in NCI-sponsored early clinical trials of new agents. This agreement calls for more extensive participation in the early clinical trials program by VA.

Non-VA Medical Centers

Under special circumstances, such as trials of particular importance to the VA or trials of rare tumor types, VA may offer mandatory veterans access to NCI-sponsored clinical trials in non-VA facilities.

7. How do veterans and their doctors find out what trials are enrolling patients and where they are located?

NCI maintains a database of clinical trials as part of its PDQ® system. PDQ provides comprehensive information on NCI-sponsored trials enrolling patients throughout the country. The database is updated monthly and provides the latest information on eligibility for clinical trials as well as physicians and hospitals participating in the trials. NCI has added a feature to PDQ that lets users search by VA facilities to identify the specific trials in which the facilities are participating. Information about how to search PDQ can be found on the Veterans Affairs and Department of Defense Beneficiaries page on the NCI's Web site at <http://www.cancer.gov/clinicaltrials/digestpage/VA-DOD> on the Internet.

Patients and the general public can call NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) to request a customized search of PDQ. Callers can ask, for example, for a search specific to a geographic location or a certain mode of treatment, as well as to the type and stage of cancer. In addition, NCI has developed a Web page that allows any user to search for clinical trials on the PDQ database directly (<http://www.cancer.gov/clinicaltrials/>).

8. What other joint activities does the agreement establish?

NCI and VA also will establish closer cooperation in planning future trials. The agreement can be accessed on the VA's Veterans Health Administration Cancer Program Web page at <http://www1.va.gov/cancer> on the Internet. More information about clinical trials is available on the clinical trials page of NCI's Web site at <http://www.cancer.gov/clinicaltrials/> on the Internet.

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Related NCI materials and Web pages:

- National Cancer Institute Fact Sheet 1.4, *NCI's Clinical Trials Cooperative Group Program* (<http://www.cancer.gov/cancertopics/factsheet/NCI/clinical-trials-cooperative-group>)
- National Cancer Institute Fact Sheet 2.5, *The National Cancer Institute's Cancer Information Service: Questions and Answers* (<http://www.cancer.gov/cancertopics/factsheet/Information/CIS>)

- National Cancer Institute Fact Sheet 2.11, *Clinical Trials: Questions and Answers* (<http://www.cancer.gov/cancertopics/factsheet/Information/clinical-trials>)
- National Cancer Institute-Designated Cancer Centers Database (<http://www.cancer.gov/cancertopics/factsheet/NCI/cancer-centers>)
- *Taking Part in Cancer Treatment Research Studies* (<http://www.cancer.gov/clinicaltrials/Taking-Part-in-Cancer-Treatment-Research-Studies>)

For more help, contact:

NCI's Cancer Information Service

Telephone (toll-free): 1-800-4-CANCER (1-800-422-6237)

TTY (toll-free): 1-800-332-8615

LiveHelp[®] online chat: <https://cissecure.nci.nih.gov/livehelp/welcome.asp>

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